REMARKS

The Office Action of March 2, 2006 has been received and reviewed. Claims 1-13 are pending and all stand rejected. Claim 1 has been amended to simply incorporate the elements of claim 9. Claim 9 is to be canceled. All amendments and cancellations were made without prejudice or disclaimer. Reconsideration is respectfully requested.

Information Disclosure Statement

UK Patent GB 2194886B, which is related to DE 371562, is included in the Information Disclosure Statement enclosed herewith.

Specification

The specification was objected to as allegedly failing to provide proper antecedent basis for the term "orally" in claim 5. Support for oral administration can be found, for instance, in paragraphs [0006] and [0020] of the specification. Nevertheless, paragraph [0034] of the specification has been amended to include oral administration of a composition comprising an oligopeptide. Support for the amendment can be found throughout the specification, for example, in the original claim 5. Withdrawal of the objection is respectfully requested.

Declaration with power of attorney

The Office Action stated that non-initialed and/or non-dated alterations had been made to the declaration. A newly executed declaration with power of attorney will be submitted prior to or upon allowance of the patent.

Double patenting

Claims 1-13 were provisionally rejected under 35 USC 101 as allegedly claiming the same invention as that of claims 1-13 of copending Application No. 11/249,541. Applicants submit that the allegedly conflicting claims have not yet been granted in a patent and therefore it is appropriate to postpone the rejection until a patent would be issued from the '541 application.

Claim rejections under 35 USC 112, enablement

Claims 1-13 were rejected under 35 USC 112, first paragraph, for allegedly not reasonably providing enablement for a composition comprising any oligopeptide comprising QGV.

Claim 3 recites admittedly enabling subject matter. Withdrawal of the rejection against claim 3 is requested.

The Office Action argues that "minor structural difference among structurally related compounds or compositions can result in substantially different or deleterious biological activities". It is acknowledged that different activities may occur if the minor structural difference takes place in a portion that is critical to maintain the structure and consequently the function of a protein. It is submitted that "QGV" or "MRTV" as recited in claim 1 is a portion that is critical to the function of the oligopeptide.

In addition, the length of the oligopeptide as claimed is not unlimited. "Oligopeptide" as defined in the specification, are peptides having from 3 to 12 amino acids joined together by peptide bonds. *See*, Specification, paragraph [0017]. Ngo et al. teaches structure predictions of proteins and polypeptide, which encompass multiple magnitudes of complexity and unpredictability as compared to the oligopeptide as disclosed in the instant application.

Further, WO 01/72831 discloses numerous oligopeptides having 3 to 12 amino acids. WO 01/72831 has been incorporated into the as-filed application by reference. *See*, Specification, paragraph [0004]. All of those oligopeptides comprising a common critical portion of amino acid sequence, for example, QGV, exhibited similar antiseptic activities. *See*, WO 01/72831, page 60-61. Therefore, also based on common knowledge in the art of oligopeptides, it is reasonable to say that a critical portion comprising 3 or 4 amino acids (a "motif" as known to the art) would maintain its activity in an oligopeptide comprising 3 to 12 amino acids.

Neither the patent statutes nor the rules require the open ended "comprising" be explicitly described. Applicants believe that the instant application reasonably provides enablement for using and making a composition comprising an oligopeptide comprising QGV or MTRV. Withdrawal of the rejections is thus respectfully requested.

Claim rejections under 35 USC 112, written description requirement

Claims 1-13 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. It is submitted that a representative description of structural and functional properties of the claimed invention has been included in the application as filed. For example, the specification provides:

> As we described in PCT International Publication No. WO 03/029292 A2 (published April 10, 2003), PCT International Publication No. WO 01/72831 A2 (published October 4, 2001), and U.S. Patent Application Publications 20020064501 A1 (published May 30, 2002), 20030119720 A1 (published June 26, 2003), 20030113733 A1 (published June 19, 2003), and 20030166556 A1 (published September 4, 2003), the contents of all of which are incorporated by this reference, compositions containing some of the oligopeptides described herein have immunoregulatory activity useful in, for example, the treatment of sepsis and other disease states and conditions.
> Specification, paragraph [0004].

The referenced patent application publications disclose numerous oligopetides comprising "QGV". Throughout the specification, descriptions of activities, functions and/or administrations are directed to oligopeptides comprising "QGV" or "MTRV". Applicants believe that the written description requirement has been fully complied with, and thus respectfully request the rejections be withdrawn.

Claim rejections under 35 USC 102

WO 01/72831 as evidenced by Merck Index

Claims 1-4, 6, 7, and 9-13 were rejected under 35 USC 102(b) as allegedly being anticipated by WO 01/72831 as evidenced by Merck Index. Applicants traverse the rejections as set forth hereinafter.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by

persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

It is acknowledged that septic shock may cause acute renal failures, and blood urea nitrogen may be increased as a result of renal failure. However, the Office has not established that septic shock will definitely cause renal failure, or that renal failure will definitely cause an increase of blood urea nitrogen concentration. As disclosed in WO 01/72831, septic shock may have many other consequences than renal failure. Further, elevation of blood urea nitrogen concentration may not necessarily result from septic shock. Therefore, elevation of blood urea nitrogen is "NOT NECESSARILY PRESENT" in the septic shock "DESCRIBED IN THE REFERENCE". As such, the Office has not met the burden of proving that lowering blood urea nitrogen concentration is an inherent property of peptide AQGV. Claims 1-4, 6, 7, and 9-13 are therefore novel over WO 01/72831.

2004/0013661 as evidenced by Merck Index

Claims 1-5 and 7-13 were rejected under 35 USC 102(e) as allegedly being anticipated by 2004/0013661 as evidenced by Merck Index. Applicants traverse the rejections as set forth hereinafter.

The Office argues that reducing blood urea concentration is an inherent property of the oligopeptide composition consisting of SEQ ID NO:2. As discussed *supra*, elevation of blood urea nitrogen is "NOT NECESSARILY PRESENT" in septic shock. Therefore, the Office has not met the burden of proving that lowering blood urea nitrogen concentration is an inherent property of peptide AQGV. As such, 2004/0013661 as evidenced by Merck Index does not anticipate all claim elements of any of claims 1-5 and 7-13. Applicants thus request the rejections be withdrawn.

If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' agent at the address or telephone number given herein.

Respectfully submitted,

Li Feng, Ph.D.
Registration No. 57,292
Attorney for Applicant(s)
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: August 1, 2006

Enclosures: Petition for Extension of Time for two months
Check in the amount of $225
Check in the amount of $180
Information Disclosure Statement

Document in ProLaw